

Serial No. 09/873,431

KOLTER et al.

PF 0000051497

A P P E N D I X I:

THE LISTING OF CLAIMS:

1. (currently amended) A process for producing an oral dosage form with sustained release of active ingredient, wherein the dosage form comprises comprising
 - a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone which acts as a binder and a matrix former, and wherein
the polyvinylpyrrolidone has a molecular weight of from 20,000 to 1,000,000, and
the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate.
 - b) at least one active ingredient,
 - c) optionally water-soluble polymers or low or high molecular weight lipophilic additives,
 - d) and, optionally, excipients,wherein the process comprises granulating a mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) is granulated by heating to a temperature of from 40°C to 130°C, and in the absence of solvents.
~~wherein the molecular weight of polyvinylpyrrolidone is between 20,000 and 1,000,000 and wherein the formulated mixture of polyvinylacetate and polyvinylpyrrolidone acts as binder and a matrix former.~~
2. (previously presented) A process as claimed in claim 1, wherein the polyvinyl acetate to polyvinylpyrrolidone ratio is 6:4 to 9:1.
3. (previously presented) A process as claimed in claim 1, wherein the active ingredient : water-soluble polymers or low or high molecular weight lipophilic additives ratio employed is from 5:95 to 85:15.
4. (previously presented) A process as claimed in claim 1, wherein polyvinyl acetate and polyvinylpyrrolidone each have a molecular weight of from 20,000 to 1,000,000.
5. (previously presented) A process as claimed in claim 1, wherein the mixture is granulated by heating to from 45 to 100°C.

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6. (previously presented) A process as claimed in claim 1, wherein the particle size of the active ingredients employed is in a range from 20 to 700 μm .
7. (previously presented) A process as claimed in claim 1, wherein the excipients employed are fillers, disintegrants and adsorbents, lubricants, flowability agents, dyes, stabilizers, antioxidants, wetting agents, preservatives, release agents, flavorings or sweeteners.
8. (currently amended) A process as claimed in claim 1, wherein fillers are selected from the group consisting of lactose, cellulose powder, mannitol, calcium diphosphate and starch are employed as excipients.
9. (previously presented) A process as claimed in claim 1, wherein the granules can be produced by employing the process of mixer granulation, fluidized bed granulation or extrusion granulation.
10. (canceled)
11. (canceled)
12. (previously presented) A process as claimed in claim 1, wherein besides the formulated mixture of polyvinyl acetate and polyvinylpyrrolidone, further release-sustaining excipients may optionally be employed before, during or after the granulation.
13. (previously presented) A process as claimed in claim 1, wherein water-soluble, water-soluble highly swelling or lipophilic excipients are employed for further modification of release.
14. (canceled)
15. (canceled)
16. (currently amended) A process as claimed in claim 1, wherein the water-soluble polymers are selected from the group consisting of: polyvinyl alcohols, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones, vinyl acetate/vinyl pyrrolidone copolymers, polyethylene glycols, polyvinylpyrrolidones, vinyl acetate/vinylpyrrolidone copolymers, or maltodextrins, and salts thereof.
17. (currently amended) An oral dosage form comprising

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- a) a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone wherein the polyvinylpyrrolidone has a molecular weight of from 20,000 to 1,000,000, and the polyvinylpyrrolidone is finely dispersed in the polyvinyl acetate.
- b) at least one active ingredient,
- c) optionally water-soluble polymers or low or high molecular weight lipophilic additives, and
- d) ~~and~~, optionally, excipients,
- wherein the mixture of a) to d) or a) to c) or a) and b) and d) or a) and b) is granulated by heating to a temperature of from 40°C to 130°C.
18. (original) An oral dosage form as claimed in claim 17, which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active pharmaceutical ingredients.
19. (previously presented) An oral dosage form as claimed in claim 18, which comprises active pharmaceutical ingredients as active ingredients.
20. (currently amended) An oral dosage form as claimed in claim 18, wherein the active pharmaceutical ingredient is selected from the group consisting of benzodiazepines, antihypertensives, vitamins, cytostatics, anesthetics, neuroleptics, antidepressants, antibiotics, antimycotics, fungicides, chemotherapeutics, urologicals, platelet aggregation inhibitors, sulfonamides, spasmolytics, hormones, immunoglobulins, sera, thyroid therapeutics, psychopharmaceuticals, antiparkinson agents, and other antihyperkinetics, ophthalmologicals, neuropathy products, calcium metabolism regulators, muscle relaxants, lipid-lowering agents, liver therapeutics, coronary agents, cardiac agents, immunotherapeutics, regulatory peptides and their inhibitors, hypnotics, sedatives, gynecologicals, antigout agents, fibrinolytics, enzyme products and transport proteins, enzyme inhibitors, emetics, perfusion promoters, diuretics, diagnostics, corticoids, cholinergics, biliary therapeutics, antiasthmatics, bronchospasmolytics, beta-receptor blockers, calcium channel blockers, ACE inhibitors, arteriosclerosis remedies, antiinflammatory agents, anticoagulants, antihypotensives, antihypoglycemics, antifibrinolytics, antiepileptics, antiemetics, antidotes, antidiabetics, antiarr-

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hythmics, antianemics, antiallergics, anthelmintics, analgesics, analeptics, aldosterone antagonists and weight-reducing agents.

21. (previously presented) An oral dosage form as claimed in claim 17, which is used to produce compressed tablets.
22. (previously presented) A drug product with delayed release of active ingredient, which is an oral dosage form as claimed in claim 17.
23. (previously presented) A drug product for delayed release of active ingredient, which is an oral dosage form as claimed in claim 17 which has been produced by compression.
24. (canceled)
25. (previously presented) The method of delaying the release of at least one active ingredient comprising producing the oral dosage form of claim 17 wherein the at least one active ingredient comprises food supplements or additives, vitamins, minerals or trace elements.
26. (canceled)
27. (new) A process as claimed in claim 1, wherein the production is either continuously or batchwise.
28. (new) A process as claimed in claim 1, wherein the granulated mixture is further processed by forced screening of the granules in the hot state or in the cooled state.
29. (new) A process as claimed in claim 1, wherein the water-soluble polymers are selected from the group consisting of alginates, pectins, galactomannans, carrageenans, dextran, curdlan, pullulan, gellan, chitin, gelatin, xanthans, hemicelluloses, cellulose derivatives, starch derivatives, maltodextrins, polyacrylic acid, polymethacrylic acid, acrylic acid/methacrylic acid copolymers, polyvinyl alcohols, high molecular weight polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers and high molecular weight polyvinylpyrrolidones.
30. (new) A process as claimed in claim 14, wherein the cellulose derivatives are selected from the group consisting of methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose and carboxymethylcellulose; and the starch derivatives are selected from the group consisting of carboxymethylstarch and degraded starch.

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31. (new) A process as claimed in claim 1, wherein the lipophilic substances are selected from the group consisting of fatty alcohols, fatty acids, glycerides, fatty acid esters, fatty alcohol esters and lipophilic polymers.
32. (new) A process as claimed in claim 15, wherein the fatty alcohol is stearyl alcohol; the fatty acid is stearic acid; and the lipophilic polymers are selected from the group consisting of ethylcellulose, cellulose acetate, acrylic ester/methacrylic ester copolymers, methacrylic acid/acrylic ester copolymers, cellulose acetate phthalate, cellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate and hydroxypropylmethylcellulose acetate succinate.
33. (new) The dosage form defined in claim 17 which comprises water or solvent in amounts of less than 5% to increase surface moisture.

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